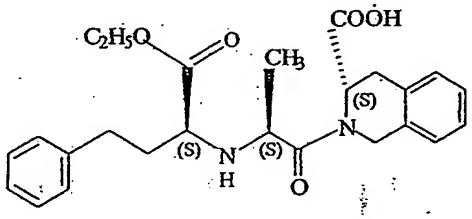
CLAIMS

1. A crystalline nitroalkane solvate of quinapril hydrochloride of formula (I) substantially free of impurities.



• HCl (I)

2. A crystalline nitroalkane solvate quinapril hydrochloride as claimed in claim 1 wherein the nitroalkane is nitromethane, said nitromethane solvate of quinapril hydrochloride exhibiting essentially the following X-ray (powder) diffraction data.

Spacing 'd'	Relative intensity
16.2471	63.5
13.8426	55.5
11.9609	57.3
9.6467	17.2
7.9468	22.4
7.5064	31.1
7.1699	30.2
6.4095	52.4
6.0561	3.1
5.5041	20.4
5.2808	33.1
5.1767	22.8
4.8704	5.7
4.6830	34.4
4.4404	100

4.0977	30.9
3.9931	69.5
3.7747	62.8
3.5972	12.9
3.5058	22.8
3.4153	8.3
3.3558	7.0
3.2676	30.7
3.2054	7.6
3.1510	9.5
3.0854	16.5
2.9772	14.5
2.9403	17.5
2.9122	12.9
2.7798	7.6
2.6670	9.0
2.6216	6.0
2.5613	10.1
2.4650	5.2
2.3933	7.9
2.2963	4.9
2.2620	2.7
2.2290	3.0
2.1672	3.5
2.1125	3.4
2.0361	2.0
1.9911	3.3
1.9714	3.4
1.8935	2.5
1.8420	2.3
1.7917	2.0

1.7630	1.3
1.6723	1.1
1.5928	0.4
1.4683	0.5

3. A crystalline nitroalkane solvate quinapril hydrochloride as claimed in claim 1 wherein the nitroalkane is nitroethane, said nitroethane solvate of quinapril hydrochloride exhibiting essentially the following X-ray (powder) diffraction data.

Spacing 'd'	Relative intensity
17.4844	87.0
16.0841	67.2
12.0996	53.3
10.0860	18.8
8.1700	29.6
7.7522	41.2
7.3814	35.4
6.5032	39.9
6.0580	2.9
5.5780	35.8
5.3973	32.0
5.2776	23.7
4.9335	19.6
4.8335	32.9
4.7627	40.5
4.5635	88.9
4.5095	69.6
4.4227	36.5
4.2021	36.0
4.0818	100.0

3.8719	30.4
3.7802	48.7
3.6435	49.5
3.4889	10.4
3.3520	20.8
3.2948	36.3
3.1526	15.3
3.1132	19.1
3.0304	49.5
2.9280	19.2
2.9080	14.1
2.7933	7.9
2.6986	10.8
2.6399	9.4
2.5715	16.7
2.5194	9.6
2.4535	4.6
2.4140	12.7
2.3567	8.5
2.3093	5.5
2.2801	6.1
2.1687	6.7
2.1303	4.5
2.0332	5.0
2.0031	6.6
1.9801	3.7
1.9395	2.7
1.8918	4.2
1.8632	3.5
1.8354	3.0
1.8110	2.4

1.7812	2.1
1.7024	1.1
1.5414	0.6
1.3867	0.4

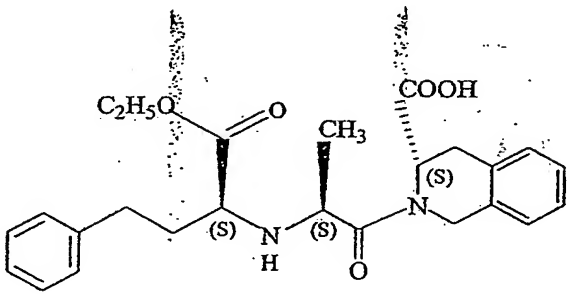
4. A crystalline nitroalkane solvate quinapril hydrochloride as claimed in claim 1 wherein the nitroalkane is nitropropane, said nitropropane solvate of quinapril hydrochloride exhibiting essentially the following X-ray (powder) diffraction data.

5

Spacing 'd'	Relative intensities
17.4327	100.0
15.4378	65.5
12.1079	49.5
10.4492	18.2
8.3626	21.3
7.9183	38.9
7.5253	27.5
6.6268	19.6
6.4583	17.2
5.6238	43.2
5.2713	27.8
5.1011	18.3
4.9816	30.7
4.8049	38.7
4.6878	52.0
4.5427	61.4
4.4480	35.3
4.3008	25.3
4.1690	68.6
4.0279	14.7

3.9483	23.9
3.7993	57.5
3.5871	15.5
3.4582	14.8
3.2960	32.0
3.1558	20.6
3.1053	26.1
3.0548	17.9
2.9559	9.2
2.9066	9.9
2.8044	10.6
2.7274	6.5
2.6357	9.4
2.5910	11.1
2.4880	5.3
2.4365	6.4
2.4053	6.0
2.3446	8.4
2.3084	5.2
2.2682	4.1
2.2075	3.0
2.1667	4.1
2.0297	13.7
2.0023	3.5
1.8765	2.2
1.8019	2.6
1.4337	2.2
1.4005	0.4

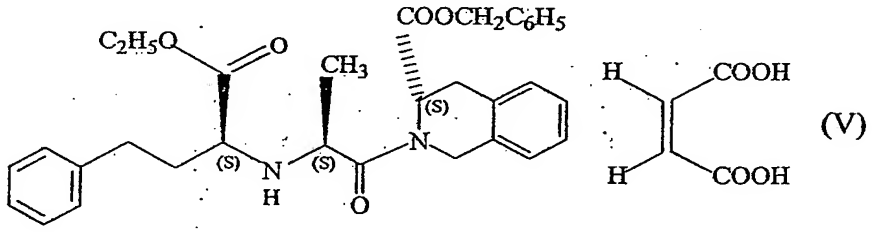
5. A process for preparation of quinapril hydrochloride of formula (I) substantially free of impurities



· HCl (I)

which comprises the steps of :

a) adjusting the pH between 7.5-8.5 of a solution of the benzyl ester maleate salt of quinapril of formula (V) in a mixture of water and an organic solvent to obtain free base compound of formula (V),



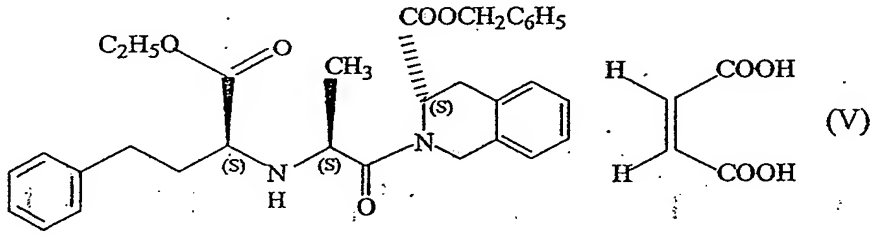
(V)

b) subjecting the free base of compound (V) thus obtained in step a) to catalytic hydrogenation in an alcoholic solvent in the presence of concentrated hydrochloric acid or hydrogen chloride dissolved in an alcoholic solvent and in the presence of catalytic amounts of Pd/C to obtain a residue containing formula (I),

c) crystallization of the residue containing compound of formula (I) thus obtained by evaporating the alcoholic solvent from step b) from a nitroalkane solvent to give crystalline quinapril hydrochloride, associated with a solvate of the nitroalkane solvent, and

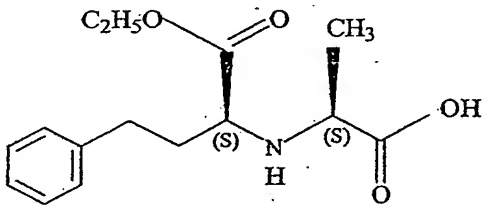
d) drying the crystalline quinapril hydrochloride nitroalkane solvate obtained in step c) at a temperature between 40^0 C and 45^0 C under vacuum to give pure quinapril hydrochloride of formula (I).

6. A process according to Claim 5, wherein the benzyl ester maleate salt of quinapril of formula (V),



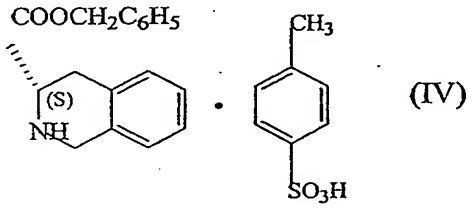
(V)

is obtained by reacting the acid halide of compound of formula (III),



(III)

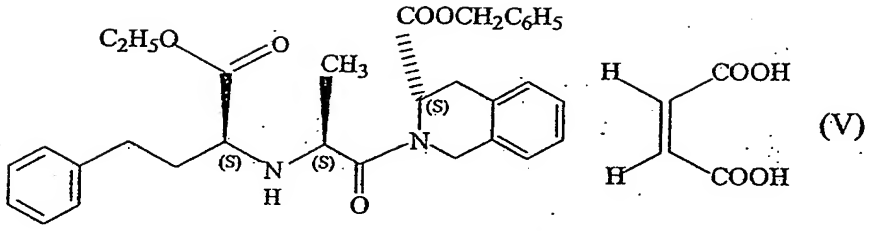
with compound of formula (IV)



(IV)

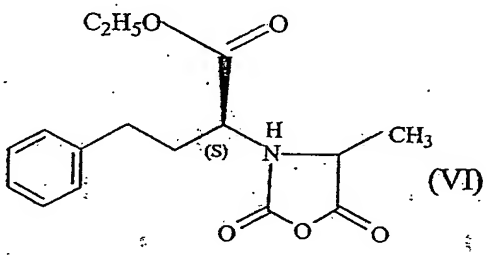
in an organic solvent and in the presence of a base followed by addition of maleic acid.

7. A process according to Claim 5, wherein the benzyl ester maleate salt of quinapril of formula (V),



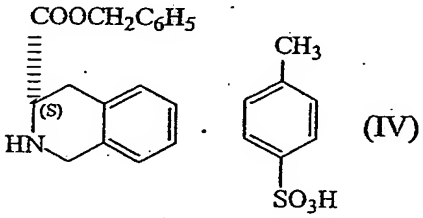
(V)

is obtained by reacting the compound of formula (VI),



(VI)

with a compound of formula (IV),



(IV)

in an organic solvent and in the presence of a base followed by addition of maleic acid.

8. A process according to step (a) of Claim 5, wherein the organic solvent is selected from a chlorinated hydrocarbon.

9. A process according to Claim 8, wherein the chlorinated hydrocarbon is selected from dichloromethane, 1,2-dichloroethane and chloroform.

10. A process according to step (a) of Claim 5, wherein the pH is adjusted using aqueous ammonia.

11. A process according to step (b) of Claim 5, wherein the alcoholic solvent is selected from methanol, ethanol, n-propanol and isopropanol.

12. A process according to step (c) of Claim 5, wherein the nitroalkane solvent is selected from nitromethane, nitroethane and nitropropane.

13. A process according to step (c) of Claim 5, wherein the compound obtained in Step (b) is dissolved in the nitroalkane solvent at room temperature.

14. A process according to step (c) of Claim 5, wherein the crystallization is carried out a temperature ranging from -15^0 C to $+ 15^0$ C.

15. A process according to Claim 14, wherein the crystallization is carried out a temperature ranging from 0^0 C to $+ 10^0$ C.

16. A process according to step (d) of Claim 5, wherein the drying is carried out under a vacuum of 5-10 mm Hg and lasts from about 60 to about 70 hours.

17. A process according to claim 6, wherein the acid halide is acid chloride or acid bromide.

18. A process according to Claim 6, wherein the organic solvent is selected from a chlorinated hydrocarbon or an alkyl acetate.

19. A process according to Claim 18, wherein the chlorinated hydrocarbon is selected from dichloromethane, 1,2-dichloroethane and chloroform.

20. A process according to Claim 18, wherein the alkyl acetate is selected from methyl acetate, ethyl acetate and butyl acetate.

21. A process according to Claim 6, wherein the base is an organic base.

22. A process according to Claim 21, wherein the organic base is selected from triethylamine, diethylamine, tertiary butylamine, and dicyclohexylamine.

23. A process according to Claim 7, wherein the organic solvent is selected from a chlorinated hydrocarbon or an alkyl acetate.

24. A process according to Claim 23, wherein the chlorinated hydrocarbon is selected from dichloromethane, 1,2-dichloroethane and chloroform.

25. A process according to Claim 23, wherein the alkyl acetate is selected from methyl acetate, ethyl acetate and butyl acetate.

26. A process according to Claim 7, wherein the base is an organic base.

27. A process according to Claim 7, wherein the base is an inorganic base.

28. A process according to Claim 26, wherein the organic base is selected from triethylamine, diethylamine, tertiary butylamine, and dicyclohexylamine.

29. A process according to Claim 27, wherein the inorganic base is selected from sodium carbonate, sodium bicarbonate, potassium carbonate, potassium bicarbonate.